REMARKS:

Claims 18-20, 25-29, 65-69, 73-78 and 80-85 are pending. Claims 18, 19, 25, 65, and 75 have been amended to more particularly point out the invention. No new matter has been added.

The Rejection Under 35 U.S.C. §112, first paragraph

Claims 18-20, 25-29, 65-69, 73-78 and 80-85 have been rejected under 35 U.S.C. §112, first paragraph, because the specification allegedly does not enable any person skilled in the relevant art to use the invention commensurate with the scope of the claims. Applicant respectfully disagrees.

The Examiner contends that it would require undue experimentation to practice the claimed invention because there is allegedly no guidance or exemplification of any correlation between the *in vitro* data disclosed in the specification and successful *in vivo* inhibition of tumor growth. Applicant maintains that one skilled in the art at the time of filing could easily determine that monoclonal antibody MA69 could kill or inhibit the growth of cancer cells using art-accepted models without undue experimentation. The relevant question is whether the experimentation is routine because, according to *In re Wands* 858 F.2d 731, "The test is not merely quantitative, since considerable amount of experimentation is permissible..." *Id.* At 736. At the time of filing, it was known that monoclonal antibodies could be used to inhibit cancer cells *in vivo* and routine experimentation could be used to determine that monoclonal antibody MA69 could kill or inhibit the growth of cancer cells *in vivo*.

Without conceding that the Examiner's contention was correct, and solely to further the prosecution of the pending claims, Applicant had informed the Examiner that *in vitro* and *in vivo* data supported the ability of monoclonal antibody MA69 to kill or inhibit the growth of cancer cells in the Amendment and Response to Office Action filed May 10, 2004

(see page 19, first full paragraph) in response to the Office Action mailed November 10, 2003. In Krueger et al., 2001, "Monoclonal Antibody Identifies a Distinctive Epitope Expressed by Human Multiple Myeloma Cells" *Journal of Immunotherapy* 24(4):334-344 (hereafter "Krueger et al."; a copy of which was submitted with the Amendment and Response to Office Action filed May 10, 2004), Applicant demonstrated that monoclonal antibody VAC69 triggers cancer-specific cytotoxicity *in vitro* in the presence of complement as well as *in vivo* in a SCID mouse model (see the abstract, Figure 4, Table 2, and page 342 at 2nd column, 1st paragraph of Krueger et al.).

The Examiner inquired as to the relationship between the monoclonal antibody VAC69 used Krueger et al. and monoclonal antibody MA69 described in the instant specification. Applicant submits herewith a Declaration of Cohava Gelber Under 37 C.F.R. §1.132 to verify that monoclonal antibody VAC69 used Krueger et al. is monoclonal antibody MA69 described in the instant specification and deposited with the American Type Culture Collection on August 3, 1999 as Accession No. PTA-450. Although the names differ slightly, the monoclonal antibody disclosed in the instant specification and used in Krueger et al. are identical. Thus, the data showing the ability of monoclonal antibody VAC69 to kill cancer cells *in vitro* and *in vivo* in Krueger et al. supports the enablement of monoclonal antibody MA69 disclosed in the instant specification to do so.

According to *In re Brana* 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995) at 1437, test results showing antitumor activity of compounds against a standard tumor model in vivo is acceptable as evidence of utility sufficient to meet the requirement of 35 U.S.C. § 112, first paragraph. The C.A.F.C. also pointed out in *In re Brana* that the testing for the full safety and effectiveness of a product is more properly left to the Food and Drug Administration and the requirements under the law for obtaining a patent should not be confused with the requirements for obtaining government approval to market a particular

drug or therapeutic method for public use. *Id.* at 1442. Thus Applicant's demonstration of the ability of monoclonal antibody VAC69 (also known as monoclonal antibody MA69) to kill tumor cells in an SCID mouse model is sufficient to enable the instant claims within the meaning of 35 U.S.C. § 112, first paragraph.

In view of the foregoing, Applicant respectfully requests that the rejection under 35 U.S.C. § 112 is reconsidered and withdrawn.

CONCLUSION

Applicant respectfully believes that the claims of the subject application are now in condition for allowance. An action passing this case to issue is courteously urged.

In the event that the Examiner is of the opinion that further discussion of the application would be helpful, the Examiner is hereby respectfully requested to telephone the applicant's undersigned representative at (212) 415-8700 and is assured of full cooperation in an effort to advance the prosecution of the instant application and claims to allowance.

AUTHORIZATION

The Applicant has enclosed herewith all fees believed to be properly assessable in this application. However, should additional fees be required by the filing of these papers, the Commissioner is hereby authorized to charge any additional fees, or to credit any overpayment, to Deposit Account No. 13-4500, Order No. 3828-4000US1.

Respectfully submitted,

MORGAN & FINNEGAN, L.L.P.

Date: January 27, 2005

By: _____
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